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**Remarks to the
Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing
Programs**

(Federal Register Vol.69, No.71, April 13, 2004, pp.19673-19732)

1. Oral fluid as alternative specimen.

- 1.1. It is proposed in the introductory part (p.19675) as well as several times further in the text that in the case of testing for marijuana, urine specimen should be collected and tested along with the oral fluid sample. This is explained by the possible environmental contamination of oral fluid. This requirement is fully unrealistic and flies in the face of the principle of selection of proper sample for workplace drug screening. More proper way would be to consider following alternative:
 - Oral fluid is not suitable for drug testing due to possibility of false positive results,
 - Existing scientific information indicated that the possibility of external contamination of oral fluid vanishes within 30 min after possible exposure.Following the second possibility, the text in the Section 8.3 (4) on the page 19702 may be changed; instead of "wait 10 minutes prior to beginning the collection process" should read "wait 30 minutes...".
- 1.2. The explanation that raised pH of oral fluid, occurring at its increased flow rate, is associated with lower concentration of drugs, concerns only basic drugs. In the case of acidic drugs the opposite is observed.
- 1.3. I am personally not convinced that THCCOOH does not occur in oral fluid. There is simply not enough hard data on this topic. The study on the occurrence of THCCOOH in oral fluid, done preferably with negative ions LC-MS-MS, is urgently needed.
- 1.4. Spitting of saliva recommended as collection method in the Section 8.3 (6) is unhygienic and hardly feasible. There is a number of saliva collecting devices on the market, which should be assessed and cleared by FDA for this purpose.

2. Subpart C - Drug and Validity Tests

- 2.1. Section 3.1. Phencyclidine is mentioned among drugs required testing. From all statistical data seems that PCP is a drug of historical importance, which does not create any social jeopardy. The inclusion of PCP in this list should be reassessed.
- 2.2. Section 3.4. In presented tables, the term "Marijuana metabolites" is used. Marijuana is one of known preparations of cannabis plant (together with hashish and

hashish oil) and cannot metabolize. Correct term would be “Cannabis related compounds” (for initial test) and “THC metabolites” (for confirmatory test).

- 2.3. Section 3.4. Very reliable and specific immunoassay tests for MDMA/MDEA has been developed by Microgenics Inc. (CEDIA). The same company developed immunoassay for 6-MAM.

3. *Subpart H – Specimen Collection Procedure*

- 3.1. Section 8.2 (7). The recommended weight of hair specimen is 100 mg. The availability of the balance should be mentioned.
- 3.2. Section 8.2 (8). It would be safer to unequivocally mark the root end of the hair sample.
- 3.3. Section 8.5 (8) and (9). Proposed procedure does not prevent the substitution of urine sample with the “Urinator” device attached to the body.